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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,141	11/07/2001	Gholam A. Peyman	42174	4651

1609 7590 06/17/2003

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EXAMINER
SHAY, DAVID M

ART UNIT	PAPER NUMBER
3739	8

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

6L

Office Action Summary

Application No.	Applicant(s)
09/986,141	Peyman
Examiner	**Group Art Unit**
d. Shay	3739

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE —3— MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on November 6, 2002.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-40 is/are pending in the application.

Of the above claim(s)____ is/are withdrawn from consideration.

☐ Claim(s)____ is/are allowed.

☑ Claim(s) 1-40 is/are rejected.

☐ Claim(s)____ is/are objected to.

☐ Claim(s)____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s).____ ☐ Interview Summary, PTO-413

☑ Notice of References Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other____

Office Action Summary

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosed is completely silent regarding the reshaping taking place without subjecting the cornea to a vacuum.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 2, 18, and 32 the antecedent of "it" is unclear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 9-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Neefe ('604).

See column 1, line 23 to column 3, and line 30 wherein there is no manipulative difference between using infrared from a laser or any other source. And the temperature must be monitored in some manner in order to determine the heat needed to maintain the temperature.

Claims 2, 4-7, 9-14, 17, 18, 20-28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neefe ('604) in combination with Warner et al. Neefe ('604) teaches a method such as claimed except the formation of a flap (note that steps predicated on the formation of a flap are also not taught). Warner et al teach the formation of a flap in a corneal recurving method. It would have been obvious to the artisan of ordinary skill to form a flap prior to the application of the mold and to apply the mold of Neefe ('604) to the stroma, since this would spare the epithelium and heat the tissue that is actually desired to be recurved – the stroma, thus producing a method such as claimed.

Claims 2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neefe ('604) in combination with Warner et al as applied to claims 2, 4-7, 9-14, 17, 18, 20-28, and 31 above, and further in view of Sand. Sand teaches the use of an infrared laser to heat the cornea in a corneal reshaping method. It would have been obvious to use the laser of Sand to heat the cornea in the method of Neefe ('604) since the wavelength of Sand will provide penetrating heat which will be concentrated in the stroma, which is the layer of the eye desired to be heated, thus producing a method such as claimed.

Claims 2, 14-16, 18, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neefe ('604) in combination with Warner et al as applied to claims 2, 4-7, 9-14, 17, 18, 20-28 and 31 above, and further in view of Kuznetz. Kuznetz teaches heating a body portion with an applicator that is heated by circulating fluid. It would have been obvious to the artisan of

ordinary skill to employ a circulating fluid to heat the mold of Neefe ('604), since this would enable a predetermined temperature to be applied for a controllable period of time, thus producing a method such as claimed.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neefe (604) in combination with Warner et al as applied to claims 2, 4-7, 9-14, 17, 18, 20-28, and 31 above, and further in view of Berry et al. Berry et al teach producing thermocouples on the coupler to monitor the temperature of the cornea (see column 12, line 60). Thus it would have been obvious to the artisan of ordinary skill to employ thermocouples on the mold of Neefe ('604) since this would allow the temperature of the cornea to be monitored, thus producing a method such as claimed.

Claims 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neefe ('604) in combination with Warner et al as applied to claims 2, 4-7, 9-14, 17, 18, 20-28 and 31 above, and further in view of Kelman et al and Thompson et al. Kelman et al teach the equivalence of corneal onlays and corneal inlays. Thompson et al teach forming an onlays with a mold. It would have been obvious to the artisan of ordinary skill to form the onlay of Thompson et al using the heated mold of Neefe ('604), since any method can be used and to employ the formed element as an inlay, since these are equivalents, as taught by Kelman et al, thus producing a method such as claimed.

Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neefe ('604) in combination with Warner et al, Kelman et al, and Thompson et al as applied to claims 32-37 above, and further in view of Kuznetz. The teachings of Kuznetz and the motivations for combination thereof are essentially those already iterated regarding claims 2, 14-16, 18, and 28-

30. Thus it would have been obvious to the artisan of ordinary skill to combine these old and well known teachings to produce a method such as claimed.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neefe ('604) in combination with Warner et al, Kelman et al, and Thompson et al as applied to claims 32-37 above, and further in view of Berry et al. The teachings of Berry et al and the motivations for combination thereof are essentially those already set forth regarding claims 18 and 19. Thus it would have been obvious to the artisan of ordinary skill to combine these old and well known teachings to produce a method such as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Shay whose telephone number is (703) 308-2215. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0944.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330

Shay/Dl

June 4, 2003